E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2021-0436; FRL-7732-03-OCSPP]

Development of Tiered Data Reporting to Inform TSCA Prioritization, Risk Evaluation, and Risk Management; Notice of Public Meeting and Opportunity to Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On July 27, 2021, EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) will hold a public meeting to engage with interested stakeholders on the development of a proposed rule for implementing a tiered data collection strategy to help inform the Agency's prioritization, risk evaluation, and risk management activities for chemical substances or mixtures under the Toxic Substances Control Act (TSCA). Currently, EPA primarily collects exposure-related data through the TSCA Chemical Data Reporting (CDR) process. EPA is interested in ensuring that data collection strategies provide information to better meet the Agency's basic chemical data needs, such as information related to exposure, health, and eco-toxicity. To this end, EPA is exploring a data reporting rule that is tiered to specific stages of the TSCA existing chemicals program: Identifying a pool of substances as potential candidates for prioritization, Selecting candidate chemicals for and completing the prioritization process, and Assessing high-priority substances through a robust risk evaluation, which may be followed by risk management actions (depending on the outcome of the risk evaluation). Feedback from the public meeting and comments received will help inform the Agency's development of a proposed rule.

DATES: *Meeting:* The meeting will be held virtually via WebEx on July 27, 2021, from 1:00 to 3:00 EDT.

Register by: Those who would like to make a comment during the meeting must register by 6:00 p.m. EDT on July 22, 2021. Those who would like to participate in listen-only mode

must register by 6:00 p.m. EDT on July 26, 2021.

Comments: Written comments, identified by docket identification (ID) number EPA-HQ-OPPT-2021-0436, must be received on or before August 15, 2021.

Accommodations: To request accommodation of a disability, please contact the meeting contact listed under **FOR FURTHER INFORMATION CONTACT**, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

ADDRESSES: Register to attend this virtual public meeting at *https://us-epa-tirered-data-reporting.eventbrite.com.*

Submit written comments to the docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2021-0436, online at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Please note that due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on the EPA/DC and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Susan Sharkey, Data Gathering and Analysis Division (7410M), Office of Pollution Prevention and Toxics, Environmental Protection Agency; telephone number**:** (202) 564-8789; email address: *sharkey.susan@epa.gov*.

For meeting logistics or registration assistance contact: Sarah Swenson; telephone number: (202) 566-0279; email address: *swenson.sarah@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (including import), process, or distribute or propose to manufacture (including import), process, or distribute chemical substances or mixtures that can be regulated under TSCA. Any use of the term "manufacture" in this document will encompass "import," the term "manufacturer" will encompass "importer," and the term "chemical substance" will encompass "byproduct chemical substance," unless otherwise stated.

This action may be of interest to other stakeholders, including non-profit organizations in the environmental and public health sectors and members of the public interested in the safety of chemical substances used in industrial, commercial, and consumer settings. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them, and is based on the Agency's previous experience with TSCA section 8(a) collections:

- Chemical manufacturing (NAICS code 325); and
- Petroleum and coal product manufacturing (NAICS code 324).

In addition to these anticipated respondents, the potentially regulated community consists of manufacturers of byproducts that are required to report under certain TSCA section 8(a) rules, including CDR. Byproduct manufacturers may be listed under a different primary NAICS activity code for a site, such as NAICS codes 22, 322, 327310, 331 and 3344, representing utilities, paper manufacturing, cement manufacturing, primary metal manufacturing, and semiconductor and other electronic component manufacturing, respectively.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through *http://www.regulations.gov* or email. Clearly mark the part or all of the information that you

claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets*.

II. Background

TSCA requires EPA to evaluate the safety of existing chemical substances via a three-stage process comprised of prioritization, risk evaluation, and risk management. EPA's website (*https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals*) provides a detailed overview of these three stages. Under TSCA, EPA is required to have at least 20 chemical risk evaluations being conducted at any given time on substances designated as high-priority substances. Therefore, EPA needs to maintain a pool of potential candidate chemical substances to ensure that there are a sufficient number of substances ready to be prioritized and, if designated a high-priority substance, to be evaluated for risk under TSCA.

Currently, EPA relies on CDR for exposure-related information which is used, along with data from other sources, to identify the potential candidate chemicals. CDR requires submission of information to EPA by manufacturers (including importers) every four years on the production and use of chemicals in commerce. These basic exposure-related data include information on the types, quantities and uses of chemical substances produced domestically and imported into the United States. EPA uses CDR data to support risk screening, chemical prioritization, risk evaluation, and risk management activities, among other activities. This information allows EPA to develop an understanding of the types, amount, end uses, and

possible exposure to chemicals in commerce. The CDR database constitutes the most comprehensive source of basic screening-level, exposure-related information on chemicals available to EPA.

CDR data, however, could be enhanced to provide more specific or relevant data to meet the exposure-related needs of the existing chemicals program. EPA needs data targeted to specific analyses at each stage of the existing chemicals program. Such data include exposure, health, and eco-toxicity information.

A. Stages of the existing chemicals prioritization, risk evaluation, and risk management program.

Identification of Potential Candidates and Selection for Prioritization: TSCA requires the systematic prioritization of tens of thousands of existing chemicals for risk evaluation. EPA is required to select a certain percentage of candidates for prioritization from chemical substances listed on the 2014 Update of the TSCA Work Plan, giving preference to chemicals with certain hazard characteristics. Aside from the statutory preferences and requirements, EPA has broad discretion to select which other chemical substances to prioritize. EPA is interested in ensuring that exposure-related information collected through CDR provides sufficient basic data to inform the potential candidate selection process. Once a chemical substance is identified as a potential candidate, EPA needs additional information to inform which of the potential candidates should be selected to enter the prioritization stage.

Prioritization: EPA formally announces when a chemical substance is to begin 9 to 12-month long prioritization stage and provides a 3-month period for the public to submit relevant information for the subject chemicals. EPA needs sufficient information to understand the use and other exposure-related scenarios in order to inform the decision of whether the chemical should be designated as high-priority substance and, therefore, enter the risk evaluation process.

Therefore, EPA is considering requiring certain necessary data be reported by chemical manufacturers (including importers) and is considering either notifying or collecting information from processors. Additional information about the candidate selection and prioritization

processes is available on EPA's website, at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritizing-existing-chemicals-risk-evaluation*.

Risk evaluation: Once a chemical is designated as a high-priority substance, EPA begins to evaluate the risk of the chemical. The purpose of risk evaluation is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. As part of this process, EPA must evaluate both hazard and exposure, exclude consideration of costs or other non-risk factors, use scientific information and approaches in a manner that is consistent with the requirements in TSCA for the best available science, and ensure decisions are based on the weight of scientific evidence. EPA needs to ensure that sufficient information is available to inform the risk evaluation, including the development of the scope of the evaluation. Information is needed in a timely manner. For example, the scope is generally published as a draft within three months of a chemical being designated as a high-priority substance, and the scope must be finalized no later than six months after the initiation of the risk evaluation process. Information is also needed to inform exposure and hazard assessments. EPA is considering requiring chemical manufacturers (including importers), processors, and distributors to submit information to EPA to support these risk evaluation activities.

Additional information about the risk evaluation process is available on EPA's website, at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca*.

Risk management: Following risk evaluation, TSCA mandates that EPA take action if the Agency determines that there are unreasonable risks to public health or the environment from chemicals currently on the market. If at the end of the risk evaluation process EPA determines that a chemical substance presents an unreasonable risk of injury to health or the environment, the Agency must immediately start the risk management rulemaking process to address the unreasonable risk. EPA needs to ensure that sufficient information is available to develop risk

management plans and actions. For chemicals in the risk management stage, the Agency is considering requiring manufacturers (including importers), processors, and distributors to report the same type of information reported during the risk evaluation stage to ensure that EPA has the most up-to-date information to inform risk management actions. For example, if a company reported using a chemical in a particular manner at the beginning of the existing chemical process, but changes occurred in some way during the stages of the existing chemical process, the company would report on those data elements that have changed.

Additional information about the risk management process is available on EPA's website, at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-existing-chemicals-under-tsca*.

B. TSCA data reporting authorities.

Under TSCA section 8, EPA is authorized to collect certain information about chemical substances. EPA is considering using the authorities under TSCA sections 8(a), 8(c), and 8(d) to develop a model rule that can be used to trigger the need to report information for each stage of the existing chemicals program.

TSCA section 8(a)(1) authorizes the EPA Administrator to promulgate rules under which manufacturers and processors of chemical substances must maintain such records, and submit such information, as the EPA Administrator may reasonably require. The information includes, to the extent that it is known or reasonably ascertainable: chemical identity and related information; manufacturing and importing exposure-related information including byproducts; processing and use exposure-related information; and existing environmental and health effects information. CDR, described previously, is an example of a TSCA section 8(a) rule.

TSCA section 8(c) requires manufacturers, processors, and distributors to maintain and, upon request, submit to EPA information such as: significant adverse health effects, consumer allegations, occupational disease or injury, and complaints of injury to the environment.

TSCA section 8(d) requires manufacturers, processors, and distributors to submit to EPA

study information that is known or reasonably ascertainable, including lists of health and safety studies and, upon request, copies of such studies. The studies do not need to be published to be included in the submission.

III. How Can I Request to Participate in this Meeting?

You may submit a request to participate in this meeting by following the information listed under **DATES** and **ADDRESSES**. If you have questions about the meeting, you may contact the technical person for meeting content questions or the meeting contact for logistics and participation questions, as listed under **FOR FURTHER INFORMATION CONTACT**. Do not submit any information in your request that is considered CBI.

Authority: 15 U.S.C. 2601 *et seq*.

Dated: July 8, 2021.

Michal Freedhoff,

Assistant Administrator,

Office of Chemical Safety and Pollution Prevention

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